IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

CHERYL AUTIN, et al,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**No. 05-2213 Ma/An**
	)	
SOLVAY PHARMACEUTICALS, INC., and HAROLD H. SHLEVIN[1], Ph.D.,	)	
	)	
Defendants.	)	

ORDER GRANTING MOTIONS TO DISMISS

On May 9, 2005, Defendants Solvay Pharmaceuticals, Inc. ("Solvay") and Harold H. Shlevin ("Shlevin") filed motions to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). On June 13, 2005, Plaintiffs Cheryl Autin, Carol Diffee, and Abigail Givhan (collectively, "Plaintiffs") filed a combined response to the motions to dismiss, and Solvay and Shlevin replied on August 1, 2005.

I. Background

Solvay is the developer, manufacturer, distributor, marketer, and/or seller of "Estratest". (Compl. ¶ 19). Shlevin, was Solvay's President and CEO, responsible for conducting the affairs of Solvay. Specifically, Shlevin managed and directed the

[1] The Complaint incorrectly identities Shlevin as "Harold H. Shelvin."

manufacturing, production, testing, inspection, labeling, marketing, distributing, and selling of Estratest. (Compl. ¶ 16.) The Food Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. ("FDCA"), requires drug companies to obtain approval from the Food and Drug Administration ("FDA") before new drugs can be marketed lawfully. (Compl. ¶ 20.) Plaintiffs bring claims for negligence and negligent misrepresentation, breach of implied warranty, unjust enrichment and restitution, violation of the Tennessee Consumer Protection Act, and common law fraud. Plaintiffs base each cause of action on two legal/factual theories: (1) the "Illegal Sales Theory" - that Estratest cannot be sold legally because it is a new drug without FDA approval and fails to qualify for the GRASE (generally recognized as safe and effective) exception (the "Illegal Sales Theory"); and/or (2) the "Fraudulent Sales Theory"- that Solvay fraudulently sold Estratest misrepresenting affirmatively and/or through omissions that Estratest had FDA approval when it did not (the "Fraudulent Sales Theory"). (Compl. ¶¶ 23,25; Combined Resp. to Mtn. to Dismiss at 3.)

II. Jurisdiction and Venue

Solvay is a Georgia corporation with its principal place of business in Georgia. Shlevin is a resident of Georgia. Plaintiffs are residents of Tennessee. The amount in controversy exceeds $75,000. Therefore, this court has diversity jurisdiction under 28. U.S.C. §§ 1331 and 1332(d).

III. Choice of Law

A federal district court is required to apply the "choice of law" rules of the state in which it sits. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941); Cole v. Mileti, 133 F.3d 433, 437 (6th Cir. 1998). "Otherwise the accident of diversity of citizenship would constantly disturb equal administration of justice in coordinate state and federal courts sitting side by side." Klaxon, 313 U.S. at 496. Therefore, this court must apply the Tennessee rule to determine which jurisdiction's law to apply.

For tort claims, Tennessee follows the "most significant relationship" rule, which provides that "the law of the state where the injury occurred will be applied unless some other state has a more significant relationship to the litigation." Hataway v. McKinley, 830 S.W.2d 53, 59 (Tenn. 1992). Both parties assume that the injury occurred in Tennessee and that Tennessee law applies. No party alleges that another state has a more significant relationship to the litigation. The court, therefore, will apply Tennessee law.

IV. Standard for Dismissal Under Rule 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) enables a defendant to file a motion to dismiss for a plaintiff's failure to state a claim upon which relief can be granted. Motions to dismiss under Fed.R.Civ.P. 12(b)(6) are designed to test "whether a cognizable claim has been pleaded in the complaint." Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 436 (6th Cir.1988). Dismissal under Fed.R.Civ.P. 12(b)(6) is appropriate when no set of facts

exists which would entitle the plaintiff to recover. Hammond v. Baldwin, 866 F.2d 172, 175 (6th Cir.1989). Essentially, it allows the court to dismiss meritless cases which would otherwise waste judicial resources and result in unnecessary discovery. See, e.g., Neitzke v. Williams, 490 U.S. 319, 326-27, 109 S.Ct. 1827, 104 L.Ed.2d 338 (1989).

In reviewing a defendant's Rule 12(b)(6) motion to dismiss, a district court should construe the complaint in the light most favorable to the plaintiff and determine whether the plaintiff can prove no set of facts in support of his claims that would entitle him to relief. Meador v. Cabinet for Human Res., 902 F.2d 474, 475 (6th Cir.1990), cert. denied, 498 U.S. 867, 111 S.Ct. 182, 112 L.Ed.2d 145 (1990). If an allegation is capable of more than one inference, it must be construed in the plaintiff's favor. Sinay v. Lamson & Sessions Co., 948 F.2d 1037, 1039-40 (6th Cir.1991).

A district court may not grant a defendant's Fed.R.Civ.P. 12(b)(6) motion to dismiss because the court does not believe the plaintiff's factual allegations. In Re Sofamor Danek Group, Inc., 123 F.3d 394 (6th Cir.1997), cert. denied, Murphy v. Sofamor Danek Group, 523 U.S. 1106, 118 S.Ct. 1675, 140 L.Ed.2d 813 (1998). It is not the court's function to weigh evidence. Miller v. Currie, 50 F.3d 373, 377 (6th Cir.1995).

The United States Supreme Court has held that “a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” Conley

v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). Thus,"[t]he Federal Rules of Civil Procedure do not require a claimant to set out in detail all the facts upon which he bases his claim." Id. at 47. "To avoid dismissal under Rule 12(b)(6), a complaint must contain either direct or inferential allegations with respect to all material elements of the claim." Wittstock v. Mark a Van Sile, Inc., 330 F.3d 889, 902 (6th Cir. 2003).

V. Analysis

Defendants[2] argue that Plaintiffs improperly seek to use state law claims to enforce the FDCA. (Solvay's Mtn. to Dismiss at 5-6.) Defendants cite § 337(a) of the FDCA, which states that "all such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States."[3] Defendants argue that private parties may not use other laws to enforce indirectly violations of the FDCA. (Solvay's Mtn. to Dismiss at 5-6.)

Plaintiffs argue that the FDA has issued rulings that Estratest is an illegal and unapproved new drug. Plaintiffs cite Breckenridge v. Solvay, 174 F.3d 1227 (11th Cir. 1999) and a notice in the Federal Register (68 FR 17953). Therefore,

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[2] Shlevin incorporates all of Solvay's arguments about preemption in Shlevin's motion to dismiss. (Shlevin's Mtn. to Dismiss at 6.)

[3] The only exception is that a state may "bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations... if the food that is the subject of the proceeding is located in the State." 21 U.S.C. §§ 337(b)(1).

Plaintiffs contend that the FDA has already exercised its expertise and that this action is ripe for consideration because judicial deference to the FDA is no longer necessary. (Combined Resp. to Mtn to Dismiss at 5-6.)

Defendants argue that Breckenridge was withdrawn by the Eleventh Circuit Court of Appeals and has no precedential value. Defendants cite Spivey v. Elliot, 41 F.3d 1497, 1499 (11th Cir. 1995) (noting that an opinion that was withdrawn by the court will not serve as precedent); Demps v. Dugger, 874 F.2d 1385, 1389 n. 11 (11th Cir. 1989) (same). Defendants also argue that Plaintiffs misstate the holding in Breckenridge and that the Eleventh Circuit specifically concluded that it was precluded from ruling on the GRASE claim. Further, Defendants contend that the cited notice in the Federal Register merely notes the regulatory status of androgen/estrogen combination drugs, including Estratest, and invites responses from interested parties. Thus, the Defendants argue that it is merely a proposal to "reclassify" the effectiveness of those drugs and not a definitive action by the FDA. (Reply to Mtn. to Dismiss at 11-12.)

Courts generally have interpreted § 337(a) of the FDCA to mean that a private right of action does not exist to redress alleged violations of the FDCA. See Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), cert. denied, 513 U.S. 965, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994) (citing Pacific Trading Co. v. Wilson & Co., Inc., 547 F.2d 367, 370 (7th Cir.1976)

("violations of the FDCA do not create private rights of action"); Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir.1993), cert. denied, 510 U.S. 1197, 114 S.Ct. 1307, 127 L.Ed.2d 658 (1994) (citing the same principle); Ginochio v. Surgikos, Inc., 864 F.Supp. 948, 956 (N.D.Cal.1994) (citing various courts that have held that "there is no private cause of action for violation of the Food, Drug, and Cosmetic Act.") Further, courts have held that plaintiffs may not use other laws to enforce violations of the FDCA indirectly.

In Mylan, the Fourth Circuit concluded that, absent an affirmative misrepresentation that a drug had been officially approved by the FDA, a Lanham Act claim alleging that the defendant had failed to disclose FDA non-approval could not stand. The Fourth Circuit noted that "permitting [plaintiff] to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market would, in effect permit [plaintiff] to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act (""FDCA"") and the regulations promulgated thereunder." Id. at 1139.

A. Illegal Sales Theory

The Plaintiffs' Illegal Sales Theory is premised on the fact that Estratest cannot legally be sold because it does not qualify for the GRASE exception and has not been approved by the FDA. The FDA, not the district court, must determine whether a drug is legally on the market. The FDA has not ruled. In

Breckenridge, the Eleventh Circuit did not reach the issue of whether Estratest qualifies for the GRASE exception. The notice in the Federal Register cited by the Plaintiffs states: "[t]he ANDAs for the Estratest products have not been approved and are still pending." Although the court notes that the notice in Federal Register does state that the FDA "no longer believes that estrogen-androgen combination drug products are effective for the treatment of moderate to severe vasomotor symptoms," the notice also states that "[a]ny manufacturer or distributor of a drug product affected by this notice is hereby offered an opportunity for a hearing to show why estrogen-androgen combination drugs should not be reclassified as lacking substantial evidence of effectiveness for moderate to severe vasomotor symptoms." (68 FR 17953 at 6,8)

The Plaintiffs' claims are based on an alleged violation of the FDCA. The FDA has not reached a definitive conclusion about the effectiveness of Estratest or whether it qualifies for the GRASE exception. Therefore, the Plaintiffs' claims based on the Illegal Sales Theory are preempted by § 337(a) of the FDCA and are dismissed. The court cannot usurp the FDA's power to evaluate the effectiveness of a drug or to approve a drug.

B. Fraudulent Sales Theory

The Plaintiffs' Fraudulent Sales Theory is premised on Solvay's fraudulently misrepresenting affirmatively and/or through omissions that Estratest had FDA approval. The

Plaintiffs allege that Solvay falsely represented that Estratest was approved by the FDA by allowing Estratest to be placed in reference publications intended only for FDA approved drugs. Specifically, Plaintiffs allege that Estratest's publication in the Physicians' Desk Reference ("PDR") and Approved Drug Products and Legal Requirements ("Approved Drugs") affirmatively markets Estratest as approved by the FDA. (Compl. ¶ 25.)

The Defendants argue that they have never marketed Estratest as an FDA approved drug. They contend that Plaintiffs have not affirmatively identified a single instance in which Solvay stated to the public that Estratest was approved by the FDA and that indirect inferences are not actionable. (Solvay's Mtn. to Dismiss at 7). Further, the Defendants argue that Plaintiffs' allegations about the PDR and Approved Drugs are misleading and submit pages from the PDR and Approved Drugs as exhibits to their reply.[4]

Solvay argues that the PDR does not state that only FDA approved drugs are included. (Reply to Mtn to Dismiss at 7.) The Foreword to the Fifth-Ninth Edition of the PDR reads:

> Physicians Desk Reference is published by Thomson PDR in cooperation with participating manufacturers. The PDR contains Food and Drug Administration ("FDA") approved

[4] Because Plaintiffs refer to and rely on the contents of the publications in their complaint, Solvay is entitled to submit them, and the court may review the documents in deciding the motions to dismiss. See Weiner v. Klasi Co., 108 F.3d 86, 89 (6th Cir. 1997.)

> labeling for drugs as well as prescription information provided by manufacturers for grandfathered drugs and other drugs marked without FDA approval under current FDA policies. Some dietary supplements and other products are also included.

Therefore, the Plaintiffs' argument that mere inclusion in the PDR fraudulently suggests FDA approval is not supported by the text of the PDR. Estratest's inclusion in the PDR does not suggest FDA approval.

Likewise, Solvay argues that publication in Approved Drugs does not mislead the public about Estratest's approval status. (Reply to Mtn. to Dismiss at 7.) Part 1, of Approved Drugs lists FDA approved drugs and Estratest does not appear on that list. Instead, Estratest appears in Part 2, which lists more than 1,600 widely used capsules and tablets. (Exhibit 2, Reply to Mtn. to Dismiss.) Plaintiffs' argument that inclusion in Approved Drugs misleads the public also fails.

Because Plaintiffs have not pled any misrepresentations by Solvay that Estratest was approved by the FDA, Plaintiffs' claims based on the Fraudulent Sales Theory are dismissed.

VI. Conclusion

Because the court holds that the Plaintiffs' state law claims based on their Illegal Sales Theory are preempted by the FDCA and that the complaint fails to allege misrepresentations supporting Plaintiffs' Fraudulent Sales Theory, all of the

Plaintiffs' claims are dismissed.

Therefore, the court GRANTS Solvay and Shlevin's motions to dismiss.

So ORDERED this 31st day of March 2006.

s/SAMUEL H. MAYS, JR.
UNITED STATES DISTRICT JUDGE